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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/516,052	03/01/2000	John Harada	02307O-077630US	3907

7590 08/13/2003

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EXAMINER
COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	24

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/516,052	HARADA ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 12 May 2003.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-77 is/are pending in the application.

4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3,9,21,22,28,29,35,36,39,42,43,47-49,54,55,58,63 and 67-77 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims withdrawn from consideration are 4-8,10-20,23-27,30-34,37,38,40,41,44-46,50-53,56,57,59-62 and 64-68.

DETAILED ACTION

The Amendment filed May 12, 2003, paper no.23, has been entered.

Claims 1, 21, 35, 47, 54 and 55 are newly amended.

Claims 74-77 are newly added.

Claims 1-77 are pending.

Claims 4-8, 10-20, 23-27, 30-34, 37-38, 40-41, 44-46, 50-53, 56-57, 59-62 and 64-68 are withdrawn from consideration.

Claims 1-3, 9, 21-22, 28-29, 35-36, 39, 42-43, 47-49, 54-55, 58, 63 and 69-77 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Objections

Claims 1, 21, 47 and 74-77 are objected to for failing to comply with 37 CFR 1.821(d), in that reference is not made to the sequence "MPIANVI" by use of a sequence identifier preceded by "SEQ ID NO:" in the text of the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Newly added claims 74-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a polynucleotide encoding a polypeptide at least 70% identical to SEQ ID NO:2, wherein the polypeptide comprises the sequence MPIANVI, and wherein the polynucleotide modulates embryo development when expressed in a plant. The claims are also drawn to transgenic cells and plants comprising said polynucleotide, and a method of modulating embryo development in a plant by transforming a plant with said polynucleotide.

The specification describes the sequence of three polynucleotides, the *Arabidopsis* LEC1 gene (SEQ ID NO:1), the *Arabidopsis* LEC1-Like gene(SEQ ID NO:19) which was initially identified in the Arabidopsis BAC clone MNJ7 by a BLAST search of an Arabidopsis database (page 40 line 28 to page 40 line2), and the *Phaseolus coccineus* LEC1-Like gene (SEQ ID NO:21). The specification also discloses that the polynucleotides of SEQ ID NO:1 and SEQ ID NO:19 modulate embryo development when expressed in a plant, as evidenced by their ability to complement a *lec1* mutation (Example 2 pages 38-40 and Example 4 pages 40-42). The *Arabidopsis* LEC1 polypeptide (SEQ ID NO:2) and the *Arabidopsis* LEC1-Like gene(SEQ ID NO:20) share no significant sequence identity in their A and C domains, but share 83.3% amino acid sequence identity in their B-domains (Harada declaration page 3), and comprise the sequence MPIANVI in their B-domains (Harada declaration page 8). The specification does not, however, describe any polynucleotide encoding a polypeptide having at least 70% overall sequence identity to SEQ ID NO:2 and comprising the sequence MPIANVI, wherein the polynucleotide modulates embryo development when expressed in a plant.

The Examiner notes that in Applicant's reply (filed May 12, 2003) to the previous rejection under 35 U.S.C. 112, first paragraph, for written description (now withdrawn), Applicant referred to the Harada declaration as indicating that the B-domain of the polypeptides encoded by the claimed polynucleotides controls the embryo development modulation function, and that the sequences flanking the B-domain can be varied greatly (reply page 7). Yet newly submitted claims 74-77 do not require any particular percent of the amino acid sequence identity be restricted to the B-domain of the polypeptides encoded by the claimed polynucleotides. Additionally, Applicant also referred to the Harada declaration as indicating that the protein K28D At4g14540 can complement a *lec1* mutation, even though K28D At4g14540 has less amino acid sequence identity (67.8%) to the B-domain of SEQ ID NO:2 than recited in the previously rejected claims (80%) (reply page 7). Yet newly submitted claims 74-77, in addition to not requiring that the 70% amino acid sequence identity be specifically localized to the B-domain, require also that the polypeptide comprise the sequence MPIANVI, which the protein K28D At4g14540 does not comprise (Harada declaration page 9). Furthermore, the Examiner notes that while 0.61% and 0.65% viable seedlings resulted from the transformation of *lec1* mutants with SEQ ID NO:1 or SEQ ID NO:19, only 0.23% viable seedlings resulted from the transformation of *lec1* mutants with the polynucleotide encoding K28D At4g14540 (reply page 7), indicating that the polynucleotide encoding K28D At4g14540, in addition to not meeting the structural limitations of the rejected claims, may not be functionally equivalent to the polynucleotides of SEQ ID NO:1 or SEQ ID NO:19. While the disclosure of SEQ ID NOS: 1 and 19 clearly describes a correlation between an embryo development modulation function and LEC1 polypeptides comprising a subsequence that comprises MPIANVI and that is at least 80%

identical to the B-domain of SEQ ID NO:2, no sequence disclosed describes a correlation between an embryo development modulation function and polypeptides comprising a subsequence that comprises MPIANVI and that is at least 70% identical overall to SEQ ID NO:2.

Newly added claims 74-77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide encoding a LEC 1 polypeptide comprising a subsequence that comprises MPIANVI and that is at least 80% identical to the B-domain of SEQ ID NO:2, does not reasonably provide enablement for a polynucleotide encoding a polypeptide comprising a subsequence that comprises MPIANVI and that is at least 70% identical overall to SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a polynucleotide encoding a polypeptide at least 70% identical to SEQ ID NO:2, wherein the polypeptide comprises the sequence MPIANVI, and wherein the polynucleotide modulates embryo development when expressed in a plant. The claims are also drawn to transgenic cells and plants comprising said polynucleotide, and a method of modulating embryo development in a plant by transforming a plant with said polynucleotide.

The specification discloses the use of two polynucleotides, the *Arabidopsis* LEC1 gene (SEQ ID NO:1), and the *Arabidopsis* LEC1-Like gene(SEQ ID NO:19), to modulate embryo development when expressed in a plant, as evidenced by their ability to complement a *lec1* mutation (Example 2 pages 38-40 and Example 4 pages 40-42). The *Arabidopsis* LEC1

polypeptide (SEQ ID NO:2) and the *Arabidopsis* LEC1-Like gene(SEQ ID NO:20) share no significant sequence identity in their A and C domains, but share 83.3% amino acid sequence identity in their B-domains (Harada declaration page 3), and comprise the sequence MPIANVI in their B-domains (Harada declaration page 8). The specification does not, however, disclose the use of any polynucleotide encoding a polypeptide having at least 70% sequence identity to SEQ ID NO:2 and comprising the sequence MPIANVI to modulate embryo development when expressed in a plant.

The Examiner notes that in Applicant's reply (filed May 12, 2003) to the previous rejection under 35 U.S.C. 112, first paragraph, for scope of enablement (now withdrawn), Applicant referred to the Harada declaration as indicating that the B-domain of the polypeptides encoded by the claimed polynucleotides controls the embryo development modulation function, and that the sequences flanking the B-domain can be varied greatly (reply page 9). Yet newly submitted claims 74-77 do not require any particular percent of the amino acid sequence identity be restricted to the B-domain of the polypeptides encoded by the claimed polynucleotides. Additionally, Applicant also referred to the Harada declaration as indicating that the protein K28D At4g14540 can complement a *lec1* mutation, even though K28D At4g14540 has less amino acid sequence identity (67.8%) to the B-domain of SEQ ID NO:2 than recited in the previously rejected claims (80%) (reply page 9). Yet newly submitted claims 74-77, in addition to not requiring that the 70% amino acid sequence identity be specifically localized to the B-domain, require also that the polypeptide comprise the sequence MPIANVI, which the protein K28D At4g14540 does not comprise (Harada declaration page 9). Furthermore, the Examiner notes that while 0.61% and 0.65% viable seedlings resulted from the transformation of *lec1*

mutants with SEQ ID NO:1 or SEQ ID NO:19, only 0.23% viable seedlings resulted from the transformation of *lec1* mutants with the polynucleotide encoding K28D At4g14540 (reply page 7), indicating that the polynucleotide encoding K28D At4g14540, in addition to not meeting the structural limitations of the rejected claims, may not be functionally equivalent to the polynucleotides of SEQ ID NO:1 or SEQ ID NO:19.

Upon considering all the evidence of record, the Examiner maintains that the disclosure of SEQ ID NOS: 1 and 19 provides sufficient guidance for one skilled in the art to select, without undue experimentation, polynucleotides that would function to modulate embryo development on the basis of their encoding a polypeptide comprising a subsequence that comprises MPIANVI and that is at least 80% identical to the B-domain of SEQ ID NO:2. However, the Examiner also maintains that the disclosure does not provide sufficient guidance for one skilled in the art to select, without undue experimentation, polynucleotides that would function to modulate embryo development on the basis of their encoding a polypeptide comprising a subsequence that comprises MPIANVI and that is at least 70% identical overall to SEQ ID NO:2, as Applicant not disclosed any such polynucleotide, or provided guidance with respect to how to vary the overall amino acid sequence identity of SEQ ID NO:2 by at least 70% to obtain a polypeptide that comprises MPIANVI and that functions to modulate embryo development.

Double Patenting

Claims 1-3, 9, 21-22, 28-29, 35-36, 39, 42-43, 47-49, 54-55, 58, 63 and 69-73 remain rejected, and newly added claims 74-77 are rejected, under the judicially created doctrine of

obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6,235,975 (May 22, 2001), for the reasons of record set forth in the office action mailed July 30, 2002.

Applicant's arguments filed May 12, 2003, have been fully considered but they are not persuasive.

The Examiner acknowledges Applicants' statement that Applicants will consider providing a terminal disclaimer after the Examiner indicates that the claimed subject matter is otherwise available. Providing a terminal disclaimer would overcome the rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

Claims are deemed free of the prior art, due to the failure of the prior art to teach or suggest a polynucleotide encoding a LEC 1 polypeptide comprising a subsequence that comprises MPIANVI and that is at least 80% identical to the B-domain of SEQ ID NO:2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
August 11, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638